K080809

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

AUG 11 2008

IEC MedSIGHT and MedBRIGHT

March 18th, 2008

1. Submitter Information:

a. Correspondent/ Distributor:

Name:	Innovative Endoscopy Components, LLC
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Fax:	(954) 217-8781
E-Mail:	info@endoscopy.md
Registration No:	1064152
Owner/ Operator No:	9026517

b. Manufacturer:

Name:	Rudolf InnoView GmbH
Address:	Am Laidhoelzle 1 D-79224 Umkirch GERMANY
Telephone:	(+49) 7665 99094
Fax:	(+49) 7665 99095
E-Mail:	info@rudolf-innoview.de
Registration No:	9615001
Owner/ Operator No:	9026517

2. Device Name:

Classification Name:	Diagnostic Devices, Endoscope and Accessories
Common Name:	Endoscopic Camera and Light Source System
Proprietary Name:	IEC MedSIGHT and MedBRIGHT

3. Classification

Classification Number:	CFR 876.1500; Class II
Product Code:	KOG, GCT

4. Indication for use:

The Innovative Endoscopy Components (IEC) MedSIGHT and MedBRIGHT is a video system for endoscopes. MedSIGHT is a color, television camera system (supplies image) and MedBRIGHT is a xenon/halogen light source system (supplies light). Both can be used with all rigid (Arthroscopes, Cystoscopes, Hysteroscopes, Laparoscopes, Ureterorenoscopes,...) or flexible (Sinoscope, Bronchoscope) Endoscopes and it is designed for surgical procedures.

5. Description of Device:

The Innovative Endoscopy Components (IEC) MedSIGHT and MedBRIGHT is a video system for endoscopes.
The IEC MedSIGHT is a endoscopic color camera system and used in a variety of endoscopic surgical procedures (orthopedic, laparoscopic, urologic, sinuscopic, plastic,...) to capture and visualize the image from the endoscope on a monitor. The system consists of a control unit and a video head. The cable of the video head connects to the control unit. The video head connects to all rigid endoscopes (like Arthroscopes, Cystoscopes, Hysteroscopes, Laparoscopes, Ureterorenoscopes, etc.) and some flexible endoscopes (Sinuscope and Bronchoscope).
The IEC MedBRIGHT is a endoscopic light source system and used with all rigid endoscopes (like Arthroscopes, Cystoscopes, Hysteroscopes, Laparoscopes, Ureterorenoscopes, etc.) and some flexible endoscopes (Sinuscope and Bronchoscope) to provide light for a high visual and photographic clarity for color rendition. The system consists of a control unit and a fiber optic cable. The fiber optic cable connects on one site with the control unit and the other side it connects to the endoscope.
All these components are designed, constructed and intended to be operated exclusively as a unit.

6. Substantial Equivalence:

K974391, Karl Storz Imaging Endovision XL Endoscopic Camera
K983279, Richard Wolf 1CCD Endocam
K023659, Richard Wolf 1CCD Endocam
K003325, KSI NCA Video Imaging System
K983566, Stryker 888 Video Camera
K994090, KSI Autoclavable Camera Head
K070266, Smith & Nephew 560 HD Camera System

K962595, Karl Storz Xenon 300 Light Source
K983628, Richard Wolf Auto LP 5123 Xenon Light Projector
K905376, Karl Storz S6000 Light Source

7. Description of Safety:

The selection of the materials has been determined through demonstrated appropriate levels of biocompatibility. The materials are similar or identical to those used for predicate devices as well as other brands legally sold in the United States.

8. Summary:

Biocompatibility, function, indications and designs have been developed to ensure the safety of this device and it is substantially equivalent to commercially approved shaver systems available for sale in the USA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

AUG 11 2008

Mr. Michael Rizzi
Innovative Endoscopy Components, LLC
731-733 Shotgun Road
FT LAUDERDALE FL 33326

Re: K080809
Trade/Device Name: IEC MedSIGHT and MedBRIGHT
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Codes: FET, GCT
Dated: July 23, 2008
Received: July 28, 2008

Dear Mr. Rizzi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080809

Device Name: IEC MedSIGHT and MedBRIGHT

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K080809